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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 033136-260

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5): 10/088351

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/CA00/01078	September 15, 2000	September 16, 1999

TITLE OF INVENTION: APPARATUS AND PROCESS FOR CONDITIONING MAMMALIAN BLOOD

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Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:

International Preliminary Examination Report and Unexecuted Declaration

21839

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JC10 Rec'd PCT/PTO 15 MAR 2002

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
UNASSIGNED 10/088351	PCT/CA00/01078	033136-260

21. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5)):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $1,040.00 (960)		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $890.00 (970)		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO $740.00 (958)		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) $710.00 (956)		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00 (962)		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890.00	
Surcharge of **$130.00 (154)** for furnishing the oath or declaration later than 20 ☐ 30 ☐ months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

Claims	Number Filed	Number Extra	Rate		
Total Claims	81 -20 =	61	X$18.00 (966)	$ 1098.00	
Independent Claims	5 -3 =	2	X$84.00 (964)	$ 168.00	
Multiple dependent claim(s) (if applicable)			+ $280.00 (968)	$ -0-	
TOTAL OF ABOVE CALCULATIONS =				$ 2156.00	
Reduction for 1/2 for filing by small entity, if applicable (see below).			+	$ 1078.00	-
SUBTOTAL =				$ 1078.00	
Processing fee of **$130.00 (156)** for furnishing the English translation later than 20 ☐ 30 ☐ months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$ -0-	
TOTAL NATIONAL FEE =				$ 1078.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00 (581)** per property			+	$ -0-	
TOTAL FEES ENCLOSED =				$ 1078.00	
				Amount to be refunded:	$
				charged:	$

a. ☒ Small entity status is hereby claimed.

b. ☒ A check in the amount of $ 1078.00 to cover the above fees is enclosed.

c. ☐ Please charge my Deposit Account No. 02-4800 in the amount of $___ to cover the above fees. A duplicate copy of this sheet is enclosed.

d. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-4800. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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45,742
REGISTRATION NUMBER

March 15, 2002
DATE

APPARATUS AND PROCESS FOR CONDITIONING MAMMALIAN BLOOD

TECHNICAL FIELD

This invention relates to a process and apparatus for treating mammalian blood by preparing a blood charge, and treating the charge to prepare conditioned charge in preparation for injecting the conditioned charge into a patient as part of a medical procedure.

BACKGROUND ART

Various treatments have been proposed for the treatment of mammalian blood *ex vivo* to condition the blood in some way before injecting the blood into a patient. Some procedures take blood from a patient, condition the blood, and then return the blood to the same patient continuously. These procedures contrast with procedures which require that the blood be taken from the patient to be treated as a batch and then returned to the patient. In batch processes there is the possibility that the blood will be given to the wrong patient as well as the dangers inherent in transferring blood from one location to another. Also, batch treatments are potentially hazardous because of the risk of blood contamination during the process of conditioning the blood and also because of the potential for infecting the operator accidentally.

The present invention is directed at the problems inherent in the batch process of treating mammalian blood.

A blood treatment process using batch treatment techniques involves three main steps. Firstly, the blood is sourced either from a donor or from a patient, who will also be the patient receiving the conditioned blood. The blood may be mixed with an anticoagulant and the blood charge must then be transferred to apparatus used to condition the charge. Finally, the conditioned charge has to be collected and prepared for injection into the patient. These steps involve the use

of needles (sharps), tubing, valves, syringes and ancillary parts and connectors. At every stage it is important to minimize risk so that the charge is moved and treated without contamination, and so that none of the charge comes into contact with the operator running the procedure.

United States Patent No. 4,968,483 which issued on November 6, 1990 discloses a prior art blood treatment apparatus which uses an oxygen/ozone gas mixture, ultraviolet radiation and heat as blood stressors to treat or condition an aliquot of blood, prior to reinjection into a patient. Prior art apparatus, however, suffer the disadvantage in that in their use, there exists repeated opportunities where an operator may be accidentally exposed to contaminated blood. Furthermore, the separate step involved in treating or conditioning a blood sample *ex vivo* increases the possibility that a conditioned blood sample may be administered to the wrong patient.

Accordingly, it is among the objects of the present invention to provide a process and apparatus for receiving a blood charge, conditioning the charge, and preparing the conditioned charge for injecting into a patient while minimizing the risk of contamination and spillage.

It is also an object of the invention to provide a disposable flask assembly for use in a machine designed to condition a charge in the flask assembly and prepare the conditioned charge ready for injection.

SUMMARY OF THE INVENTION

In one of its aspects, the invention provides apparatus for conditioning mammalian blood for subsequent use in a medical procedure. The apparatus includes a cabinet having a secure environment and a door providing the only access to the environment. An input system is provided for transporting a blood charge from a source to the cabinet and a flask is removably contained in the secure environment and coupled to the charge input system to receive the charge.

Stressors are coupled to the cabinet and positioned for operation to create a conditioned charge in the flask. An output system is coupled to the flask and includes a receiver for the conditioned charge.

The apparatus includes an automated control system operable upon closing the door to lock the door and to then condition the charge, and to then cause the charge to move from the flask to the receiver. As a result, a charge from the input system is conditioned and delivered to the receiver, the door is then unlocked and the conditioned charge is ready to be removed and used to complete the medical procedure.

In another of its aspects, the invention provides a cabinet for use in conditioning mammalian blood for subsequent use in a medical procedure. A blood charge is conditioned in a flask and the cabinet has a front defining a front recess and a top defining a depression adjacent to the front recess. A door is hinged for movement between an open position and a closed position in which the front recess and the depression are covered by the door to create a secure environment, and a lock is coupled to the cabinet and to the door to lock the door in the closed position. A cavity extends downwardly from the top depression within the secure environment, and is adapted to receive the flask. A control system is coupled to the door lock to sense the condition of the door to establish that the flask is securely positioned in the cabinet and that the door is locked before the charge is conditioned. The charge can then be conditioned in the flask securely within the cabinet.

In yet another of its aspects, the invention provides a cabinet for use in conditioning mammalian blood for subsequent use in a medical procedure. A blood charge is conditioned in a flask and the cabinet has a front, a top, and a door hinged for movement between an open position and a closed position in which at least a portion of the front and a portion of the top are covered by the door to create a secure environment. A lock is coupled to the cabinet and to the door to lock the door in the closed position, and a cavity extends downwardly from the top wall within the secure environment to receive the flask. A control

system is coupled to the door lock to sense the condition of the door to establish that the flask is in the secure environment within the cabinet, and that the door is locked before the charge is conditioned.

In still another of its aspects, the invention provides a flask assembly for use in apparatus having a cabinet made to receive the flask assembly for conditioning mammalian blood. The flask assembly includes a flask in the form of an envelope defining a substantially enclosed volume, and including a top and a bottom. The top has an access opening and an outlet, and a connector assembly is coupled to the top of the flask. A probe extends from the connector assembly, through the access opening and has a top end and a leading end. The probe is sealed in the access opening and defines an input lumen for transporting a blood charge to the bottom of the flask, an output lumen for transporting conditioned charge from the bottom of the flask out of the flask, and a gas lumen for feeding gas into the flask to condition the charge when a charge is in the flask. The connector assembly includes outlet tubing coupled to the outlet to lead spent gas out of the flask, and inlet tubing coupled to the gas lumen. A pair of gas connectors is coupled to the platform and connected to the respective gas inlet tubing and to the gas outlet tubing to make gas connections when the flask assembly is mounted in the apparatus. As a result, when the flask is engaged in the cabinet, the gas connections engage a gas supply system for conditioning the charge in the flask before removing the conditioned charge.

In yet another aspect of the invention, a process is provided of treating mammalian blood in a blood charge to provide a conditioned charge for giving to a patient in a medical procedure. The process includes the steps of providing an automatic apparatus for treating the blood charge to create the conditioned charge, and for presenting the conditioned charge ready for use. The apparatus has a secure environment, a door controlling access to the environment, a flask, and stressors arranged to operate on a charge in the flask in the controlled environment. The blood charge is transported into the secure environment through thermoplastic inlet tubing for deposit in the flask, and the tubing is then

sealed and severed. Next the part of the inlet tubing outside the secure environment is removed and the operation of the automatic apparatus is initiated so that the stressors will operate on the charge for a predetermined period, thereby stressing the charge in the flask while maintaining the secure environment. The apparatus is then given time to transport the conditioned charge from the flask to a receiver, and the door is opened to provide access to the receiver for use to give the conditioned charge to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention, in all its aspects, will be more fully understood with reference to the following drawings taken in combination with the description. In the drawings,

Figure 1 is an isometric view of apparatus used in practicing a process of conditioning blood charges in accordance with a preferred embodiment of the invention and including a cabinet;

Figure 2 is an isometric view of a disposable flask assembly adapted for use with the apparatus;

Figure 3 is a schematic side view of the flask assembly in position in the cabinet and showing structure used to condition the charge;

Figure 4 is an exploded isometric view of the flask assembly showing details of the construction; and

Figure 5 (drawn adjacent Figure 3) is a sectional view on line 5-5 of Figure 4 and drawn to a larger scale.

DESCRIPTION OF THE BEST MODE

The invention will be described initially with reference to Figure 1, which shows the apparatus generally, and then more detail will be given with reference to further drawings. As seen in Figure 1, apparatus, designated generally by the numeral 20, includes a cabinet 21 having a front 22 and an inclined top 24. A hinged door 26 is attached to the cabinet 21 to one side of the front to move

about vertical hinges 28 between an open position shown in Figure 1, and a closed position (not shown) where it covers a front recess 30 and a top depression 32. The door is equipped with a locking bar 34 which engages in a recess 36 where it can be retained to hold the door in the closed and locked position to create a secure environment inside the cabinet 21.

As will become evident from further description, the apparatus 20 is shown after it has been prepared for use to condition a blood charge in a accordance with the process of the invention. The apparatus 20 will be described in this position to provide a general understanding of the apparatus and then in more detail with reference to the process and subsequent Figures.

The cabinet 21 is designed to be secure while the charge is being conditioned, as will be explained. The apparatus 20 includes an identification system 37 so that the apparatus 20 can be used by an operator only after a patient has been designated and identified by the apparatus by way of a discrete smart card (not shown) which has to be inserted by the patient in a first slot 38. A second smart card is inserted by the operator in a second slot 40. The patient keeps the patient's smart card so that the apparatus can be used only by the operator in the presence of the patient until the apparatus is ready to treat another charge. The smart cards can be used to store data developed during operation of the apparatus and can become a permanent record of the procedure.

A third slot 42 in a printer door 44 will produce a printed record of the treatment as required.

The operator controls the apparatus using a graphical display terminal (GDT) 46 having a touch screen interface pad overlaid on the GDT. The GDT serves to interrogate the operator to ensure that every required step is completed in the required sequence. Errors and instructions are also available on the GDT.

As mentioned, the door 26 can be moved into a locked and closed position to cover the front recess 30 and the top depression 32. In the position shown in Figure 1, a sterile flask assembly, designated generally by the numeral 48, has been lowered into the cabinet such that part of the assembly 48 can be seen projecting

upwardly into the depression 32. An input syringe 50, and an output syringe 52 have been removed from the assembly 48 ready for use. The input syringe 50 is used to source a charge and pass the charge through thermoplastic inlet tubing 54 to a flask 56 which can be seen in Figure 2. After treatment in the flask 56, the conditioned charge is drawn through outlet tubing 58 from the flask 56 into the syringe 52 by an actuator 60, as will be explained later. For the moment it is sufficient to understand that there are three stages to the treatment. Firstly, the charge is sourced and passed by syringe 50 to the flask 56 (Figure 2). Next, treatment takes place in the flask 56 and then the conditioned charge is drawn automatically from the flask into the output syringe 52 ready for injection into the patient. All of these steps are controlled by the apparatus 20 in such a way that there is a limited risk of contamination of the charge, and of exposing the charge to the operator. Further the patient is identified by the identification system 37 in such a way that if the charge is sourced from the patient for subsequent return to that patient, the treated charge will be available only when the patient presents his/her smart card to thereby ensure that the right patient gets the charge.

Reference is next made to Figure 2 to describe the main features of the flask assembly 48 as it would appear in a sterile condition ready for placement in the cabinet 21 (Figure 1). The flask assembly 48 will be supplied in a sterile container which will also include most of the items needed for the procedure. These will include needles, tubing, gauze etc. as is commonly done in medical procedures requiring sterile items for the procedure.

The assembly 48 is made up of two main parts, namely the flask 56 and a connector assembly 62 which serves to carry components used in the treatment procedure. The assembly 48 is shown as it would be placed in the cabinet 21 (Figure 1), with the input syringe 50 and output syringe 52 mounted side-by-side on the connector assembly 62. The assembly 62 is shown from the back as opposed to from the front in Figure 1. It will be seen that the connector assembly includes an overhanging portion 64 which will meet parts of the apparatus contained in the cabinet 21 when the flask assembly 48 is lowered downwardly

into the cabinet 21. As will be described, electrical and gas connections are made automatically when the assembly 48 moves into its final position in the cabinet 21. Also, the overhanging portion 64 provides clearance under the portion 64 to allow the inlet tubing 54 to be fed from the input syringe 50 to a supply probe 65 (Figures 3 and 4).

The syringes 50 and 52 are conveniently stored on the connector assembly 62 between a central shaped mound 66 (Figure 1) and respective locators 68 and 70 which are sufficiently flexible to allow the syringes to be engaged and held in place. Further location is provided by respective channel portions 72, 74 which receive respective flanges 76, 78 on the syringes 50 and 52. This interengagement locates the syringes 50, 52 longitudinally but does not interfere with vertical removal of the syringes 50, 52.

As seen in Figure 3, the flask assembly 48 is located in the cabinet 21 by a shelf 80 having an opening 81 for the flask 56, and below the shelf, a locator 82 having an opening 84 which is also proportioned to receive the flask 56 loosely. The connector assembly 62 rests on the shelf 80 about the opening 84 to locate the flask assembly 48 vertically and in proper relationship with two of the stressors to which the charge is to be subjected. One of these stressors is heat supplied by an infrared (IR) heater 86, another is ultraviolet (UV) light provided by an UV radiator 88 positioned about the flask 52. Also, in the process of lowering the flask assembly 48 in the cabinet 21, the overhanging portion 64 of the connector assembly 62 brings electrical connectors and gas supply connections together as will be explained after describing Figure 4.

Figure 3 also shows the shape of the flask 56. It extends about a longitudinal axis 89 and has a generally cylindrical main portion 90. A transitional portion 92 extends from the portion 90 to a cup 94 proportioned to receive about 12 ccs of charge from the input syringe 50 (Figure 1).

The supply probe 65 will be described more fully with reference to Figure 5. For the moment it is sufficient to understand that the function of the probe 65 is to supply charge to and remove conditioned charge from the flask 56. Also, a

mixture of ozone and oxygen is fed through a lumen in the probe 65 and a temperature sensor is provided in the probe 65. Heat from the IR heater 86 causes the charge to heat and that together with the gas supply, causes the charge to bubble and fill the flask 56. The large surface area so formed is then subject to UV light from the radiator 88. These stressors are used to condition the charge before it is delivered by the apparatus to the output syringe 52, (Figure 1).

The probe 65 is located centrally in the cup 94 by a solid extension 96 at the end of the probe 65. The extension fits closely inside a cylindrical socket 98 formed in the bottom of the flask 58, and extending from the cup 94. The extension 96 is placed in the socket 98 during assembly and the socket is crimped from the outside to retain the extension 96 in the socket 98 and to thereby secure the supply probe 65 in the flask 56.

The flask 56 is essentially an envelope made by blow moulding a parazon of low density polyethylene (LDPE) and has an internal volume that is about 70 times that of the charge. The walls are translucent to allow penetration of the UV light stressor.

Reference is next made to Figure 4 which is an exploded view of the flask assembly 48 with the syringes 50 and 52 included. This assembly includes parts of several systems. Firstly an input system made of parts associated with receiving a charge and placing it in the flask 56 ready for conditioning it. Next, an output system is made up of parts related to extracting the conditioned charge from the flask 56, and lastly, parts related to gas supply and recovery system.

The charge is received in the input syringe 50 which is connected by the thermoplastic tubing 54 to an elbow 102 forming part of the probe 65. This elbow leads to an intake lumen 104 formed in an extruded main body 106 which can be seen in the cross-sectional view, Figure 5. This view is taken on line 5-5 of Figure 4. The intake lumen 104 extends to a leading end 108 of the probe adjacent the extension 96. Consequently, the charge can be fed into the cup 94 of the flask 56 by actuating the syringe 50 to move the charge through the inlet tubing 54, through the elbow 102, and then via the lumen 104 into the cup 94.

The second set of parts is related to removing the conditioned charge. The syringe 52 is the prime mover so that when it is actuated, the charge is drawn from the cup 94 into a return lumen 109 at the end 108 of the probe 65. The charge then passes through the lumen 109 leaving via an elbow 110 which in turn leads to outlet tubing 58 and to the syringe 52.

The third set of parts mentioned above relate to a gas supply and recovery system that creates ozone from oxygen and supplies and removes an ozone/oxygen mixture. Oxygen from a replaceable oxygen supply cartridge 114 passes through an ozone generator (not shown) built into the cabinet 21 (Figure 1). Connections to the flask assembly 48 are made automatically when the assembly 48 is lowered into the cabinet as described previously. To facilitate these connections, a pair of nipples 116 (one of which can be seen in Figure 4) engage in suitable receptors (not shown) in the cabinet. The nipple that can be seen in Figure 4 is connected to gas exhaust tubing 118 which leads to an in-line filter 120 having fittings for sealably connecting to a cup 122 formed in a top 124 of the flask 56. The exhaust gas from the process is carried by these parts to an exhaust system as is conventional when using ozone.

The connector assembly 62 includes a moulded platform 126 shaped to carry the various components. As indicated in Figure 4, the outlet filter 120 is normally mounted in a holder 128 shaped to receive the disk-shaped filter 120.

The connection to the gas supply is made using the hidden nipple 116 which supplies gas to a gas inlet tubing 130. In turn, the tubing 130 directs gas to an in-line filter 132 which is associated with standard connections to send the gas to a gas supply tubing 134. The filter 132 is arranged to engage in a support 137 formed in the platform 126, and an elbow 135 on the probe 65 is connected to the tubing 134 to lead the gas to a gas lumen 136 in the extruded probe main body 106. This lumen, like the intake lumen 104 and return lumen 109, leads to the end 108 of the main body which will be submerged in charge when the charge is entered through the lumen 104.

The probe 65 also locates a temperature sensor 138 exposed near the end

108 through a side opening 140 cut into the side of the main body 106. A sterile sleeve 142 of very thin filmic plastics material encloses the sensor, but because the sleeve 142 is thin, there is a rapid temperature transfer to allow the sensor 138 to respond quickly to changes in temperature.

The sensor 138 is connected by two wires in the form of a conductive ribbon 144 which extends through a larger lumen 146 (Figure 5) in the probe 46, and then to a connector 148 mounted on the platform 126. This connector 148 is adapted to engage a corresponding sliding connector 150 (Figure 3) mounted in the shelf 80 of the cabinet 21. The connector 150 cooperates with the connector 148 to connect the temperature sensor 138 to a control system indicated generally at 151 in Figure 1 and contained in the cabinet 21 (Figure 1). The connectors 148,150 to the temperature sensor 138 preferably include a 4-point electrical connection (two connections to each contact) to ensure that electrical connections to the sensor 138 are made securely, and to permit the detection of a bad connection.

The assembled supply probe 65 is passed through a receiver 152 formed in the top 124 of the flask 56, and the extension 96 at the leading end of the probe 65 is manoeuvred into the socket 98 under the cup 94 of the flask 56. The socket 98 is then crimped from the outside sufficiently to positively locate the extension, and hence the probe, relative to the flask 56. At the same time a seal 154 under a collar 156 on the outer end of the main body 106 is brought to bear against the receiver 152 and held in compression while the socket 98 is crimped. As a result the probe is sealed in the flask with a gas tight seal.

After this assembly, the platform 126 and the parts mounted on the platform are attached to a cover 158. This is done by the use of two self-tapping screws 160 (one of which is shown) which pass through openings 162 and engage in respective bosses 164 formed in the platform 126.

The sub-assembly of the platform 126 and the cover 158 is then attached to the flask 56 using snap-fitting structure 166 formed on the flask 56 and on the cover 158. This structure is discontinuous around the flask so that there is only

one way to attach the sub-assembly to the flask 56 thereby ensuring that the parts line up correctly to engage the cup 122 on the flask 56 and to provide the necessary clearance under the overhanging portion 64 of the connector assembly 62 for the various tubing, gas connections and electrical connections.

The flask assembly 48 then receives the syringe locators 68 and 70 which snap into respective slots 168, 170 formed in the top of the cover 158. The outlet tubing 58 is then fed through an opening 172 at the back of the cover 158 and attached to the syringe 52. Similarly, the inlet tubing 54 is attached to the syringe 50 and the syringes are engaged on the cover 158 to be held in place (as previously described) by the combinations of the mound 66 with the respective locators 68 and 70.

The completed flask assembly 48 is sterilized and packaged for use as mentioned earlier.

The main structural details have been described. Some details have been omitted because they are more readily described with reference to the process of conditioning the charge using the apparatus. That process will now be described and those parts of the structure that have not been mentioned will be included in this part of the description.

The process in general is designed to source suitable mammalian blood either by using compatible blood or by using blood taken from a patient who is to receive the treated blood. This process will be described for the latter case but is not to be limited to that case.

The apparatus must be readied for use by placing the operator's smart card in the slot 40. Optionally, the operator's smart card may only be effective if used in conjunction with a personal identification number (PIN) input via the GDT 46. A patient's smart card, which may be included with the package containing the flask assembly 48, is given to the patient for the patient to place the card in the slot 38. The GDT 46 then proceeds to present instruction, error messages, and comments as the procedure progresses.

Once this is done, the door 26 is unlocked by the control circuit, and a new

flask assembly 46 is removed from its sterile package and lowered into a cavity in the cabinet to take up the position shown in Figure 1 and further illustrated in Figure 3. At this point the syringes 50, 52 are in place on the connector assembly 62.

Next the input syringe 50 is lifted from its position on the connector assembly 62 and placed conveniently with the inlet tubing 54 passing through a heat sealer 174 which is attached to the cabinet 21 for use to seal and sever the inlet tubing 54 as will be explained. The inlet tubing 54 has a locator 176 mounted on the tubing to position the inlet tubing 54 in the sealer 174.

The output syringe 52 is then removed in similar fashion and placed vertically as shown in Figure 1. The syringe 52 is located in a fixed mount 178 using the flange 78 and a syringe operator 180 extends downwardly and is engaged in an actuator 182 which can be driven along a slide 184 by a motor and drive (not shown) in the cabinet. The actuator 182 that receives the syringe operator 180 is intentionally oversized in the vertical dimension to allow easy installation of the output syringe 52 and removal of the output syringe 52 without affecting the position of the syringe operator 180 relative to the body of the output syringe 52. This operation will be described with reference to removing a conditioned charge.

The outlet tubing 58 associated with the syringe 52 is led through a second heat sealer 186, and a locator 188 on the tubing 58 positions the outlet tubing in the sealer 186. This sealer 186 will be used after the conditioned charge is drawn into the syringe 52, as will be explained.

The heat seal locators 176,188 allow the user to accurately and repeatably position the thermoplastic tubing 54,58 for proper automatic sealing and severing. The locators 176,188 thus ensure that the tubes 54,58 are not misaligned or inserted improperly in the sealers 174,186, and allow the control system to detect that the tubing 54,58 is properly placed. The locators 176,188 minimize the likelihood that tubing 54,58 will get caught in the door by controlling the length and positioning of tubing inside the cabinet. In one possible construction, the

locators 176,188 consist of two pieces of metal film positioned in an opposing orientation along each side of the tube. The metal film advantageously allows quick sealing of the tubes 54,58 and the prevention of contamination. It is to be appreciated, however, that other tube locator constructions are also possible.

A message on the GDT 46 (Figure 1) reminds the operator to close the door 26 and the door lock bar 34 is engaged. The control system 151 (Figure 1) activates the door so that the cabinet can be opened only by using the two smart cards. Consequently the smart card carried by the patient is necessary so that no one other than the patient can cooperate with the operator to get into the cabinet 21. The patient's smart card is preferably attached to the patient's wrist in a semi-permanent fashion using a suitable band of the type commonly used in hospitals.

The input syringe 50 is still in the condition shown in Figure 2. A T-connector 190 includes a valve controlled by a selector 192 which connects the body of the syringe to either an in-line port 194, or a side port 196 at right angles to the axis of the body. The inlet tubing 54 is attached to the port 196 and the port 194 is available.

A needle (not shown) is attached to port 194 and about 2 ccs of an anti coagulant (preferably sodium citrate) is drawn into the syringe. The needle is discarded into a sharps container and then a tubing assembly 198 (Figure 1) is attached to the in-line port 194. This assembly 198 includes a one-way valve 200, to avoid back flow, and at its leading end an angel wing collector set 202 is ready for engagement into the patient to collect blood. The collector set is used to draw 10 ccs of blood into the syringe 50 where it is mixed with the sodium citrate by rocking the syringe gently to create a blood charge for treatment in the process according to the invention.

Next, the selector 192 on the T-connector 190 is operated to connect the body of the syringe 50 with the side port 196 leaving the tubing assembly attached but inoperable. The syringe 50 is then inverted (i.e. placed with the T-connector uppermost) and about 3 to 4 ccs of sterile air are drawn from the flask 56 into the syringe. The syringe 50 is then again inverted so that the air is above the charge

and the syringe is then operated to drive the charge through the inlet tubing 54 and into the flask 56 driven by the air in the syringe. As a result the inlet tubing is cleaned out as the air follows the charge.

It is now time to discard the input syringe 50 and associated parts. Before this can be done, the syringe 50 has to be separated from the cabinet 21 to which it is connected by the inlet tubing 54. This is achieved by operating the heat sealer 186 which seals and severs the tubing under the influence of heat.

Once this step is completed the input syringe 50 and attached parts are discarded.

It should be noted that the door 26 (Figure 1) has not been opened during this procedure and that the charge of blood and sodium citrate has been received in the cup 94 of the flask 56 (Figure 3). It should be noted that although the process is to condition blood, to be accurate the process treats blood as the prime part of a charge which also contains an anticoagulent, (or any other additive). Consequently the term "charge" is used to describe a batch made up of blood and at least one additive. However if circumstances arise in which blood can be treated alone, such use is within the scope of the term because mammalian blood continues to be the subject of the treatment and it is not intended to exclude such an interpretation.

The next stage of the process can now begin. The control system 151 in the cabinet 21 takes over and starts the IR heater 86 (Figure 3) to elevate the temperature of the charge. This is one example of a process known generally as "stressing" the charge and the IR radiator is known as a "stressor". The temperature is elevated to about 42.5°C and is controlled from a reading originating with the temperature sensor 138. Once the selected temperature has been reached, the control system activates a second stressor. An ozone generator sends an oxygen/ozone mixture into the flask 56 through the probe 65 as described earlier. Also, the UV light source 88 (third stressor) is activated so that the heated charge is simultaneously stressed by the ozone/oxygen mixture and by the UV light simultaneously for about 3 minutes. The bubbled charge fills the

flask and is then allowed to settle and cool for about 7 minutes so that bubbles in the charge will tend to settle.

At this point the charge has been conditioned and the GDT 46 (Figure 1) will respond to the control system to give the operator a message that the smart cards will be needed to withdraw the conditioned charge. However the door 26 (Figure 1) will not open until the charge is available in the output syringe 52 even if the cards are inserted at this stage. On the other hand, if the charge is in the syringe (as will be explained) and ready for removal, the door 26 will remain closed unless the cards are inserted.

Next the apparatus will commence the step of moving the charge from the flask 56 (Figure 3) to the output syringe 52 (Figure 1). This is done automatically by the actuator 182 seen in Figure 1, which draws the operator 180 downwardly. A knocker 204 is then driven to tap the syringe at a rate of about 1 Hertz to break any resident bubbles. The knocker consists of an impact tool 205 mounted in the recess 30 of the cabinet, and driven to strike the syringe 52 gently thereby deflecting the syringe sideways to store energy in a coil spring 207 positioned on the opposite side of the syringe from the tool 205. The energy in the spring then causes the spring to rebound thereby pushing the syringe back into contact with the impact tool 305 ready for the next impact. The frequency can be varied and will to some extent depend on the geometry and mass of the parts. However, it has been found that a frequency of 1 Hertz with a spring having a spring rate of between about 0.1 to 5N° provides good results.

Next the actuator 182 and bubble detector are operated to express some of the contents of the syringe 52 back into the outlet tubing 58 until there remains a volume of 9 to 10 ccs of conditioned charge. If following the operation of the actuator 182, there are still bubbles in the syringe 52 after the knocking process, the control system will detect this, via the bubble detector, and repeat the knocking process until the bubbles are gone, with the bubbles removed in a closed loop. A sensor (not shown) in the heat sealer 186 tells the control system in the cabinet 21 that the system is ready to seal the outlet tubing 58 in similar fashion to

the seal made on the inlet tubing 54 as previously described.

As indicated, the actuator 182 into which the plunger end of the operator 180 is inserted has been designed to be intentionally wide in the vertical direction. This configuration allows the user to easily insert the plunger end of the operator 180, but, more importantly, it allows the user to remove the syringe 52 without affecting the operator 180. This ensures that no undue force will be exerted on the operator 180 which could result in the operator 180 moving and causing a leak of blood.

The process has now reached a critical point. If the patient has not inserted the patient's smart card by now, the apparatus will wait only for a predetermined time (usually about 20 minutes) before aborting the process. If the process is to be aborted, a message will appear on the GDT 46 (Figure 1) and the control system will cause the actuator 180 to drive the syringe operator 182 so that the conditioned charge is returned to the flask 56 before shutting down the process. Once this is done the operator can open the door 26 using only the operator's card so that the flask 56 and its contents can be discarded to ready the apparatus 20 for a new process.

If the patient presents the card in time, the respective smart cards are inserted into the slots 38, 40 and in the preferred case the sealing sealer 186 is a heat sealer which will seal and sever the tubing 58, the door 26 will open, and the output syringe 52 is then available for removal from the cabinet 21. However, before this is done, the patient must be prepared for the injection of about 8 to 9 ccs of conditioned charge. Normally [local anaesthetic is optional], the patient will be anaesthetized in the gluteal muscles using a suitable needle and performing the standard procedure for ensuring that the needle has not been inserted into a blood vessel. Next, the anaesthetic syringe is removed and the needle is left in the patient. The output syringe 52 is then taken to the anaesthetic needle and after discarding the remaining tubing 58 from the heat sealing operation, the output syringe 52 is attached to the anaesthetic needle and the conditioned charge is fed into the patient slowly. After this procedure, the output syringe and attached

needle are discarded.

The apparatus can then be prepared for the next procedure by removing the remains of the flask assembly 48.

It will now be evident that the process can be used to treat mammalian blood in a blood charge to provide a conditioned charge for giving to a patient in a medical procedure. In general the process includes the steps of providing an automatic apparatus for treating the blood charge to create the conditioned charge, and for presenting the conditioned charge ready for use. The apparatus has a secure environment, a door controlling access to the environment, a flask, and stressors arranged to operate on a charge in the flask in the controlled environment. The blood charge is transported into the secure environment through thermoplastic inlet tubing for deposit in the flask, and the tubing is then sealed and severed. Next the part of the inlet tubing outside the secure environment is removed and the operation of the automatic apparatus is initiated so that the stressors will operate on the charge for a predetermined period, thereby stressing the charge in the flask while maintaining the secure environment. The apparatus is then given time to transport the conditioned charge from the flask to a receiver, and the door is opened to provide access to the receiver for use to give the conditioned charge to the patient.

Improved control can be provided by the preferred use of smart cards, as explained, and by the use of thermoplastic tubing and heat sealers to ensure that the secure environment is maintained. Also, the process can be enhanced by use of the knocker to reduce the time needed to dissipate the bubbles in the conditioned charge.

It will be appreciated that the described embodiments of the apparatus, and of the process associated with the apparatus, can be varied within the scope of the claims and that such variations are within the scope of the invention.

INDUSTRIAL APPLICABILITY

The invention claimed is useful in practicing procedures in which

mammalian blood is to be conditioned for subsequently giving to a patient for treating or preventing various medical conditions.

Although the disclosure describes and illustrates various preferred embodiments, the invention is not so limited. Many modifications and variations will now occur to persons skilled in the art. For a definition of the invention reference may be had to the appended claims.

SUBSTITUTE CLAIMS

1. Apparatus for conditioning mammalian blood for subsequent use in a medical procedure, the apparatus including:

a cabinet having a secure environment and a door providing the only access to the secure environment;

an input system for transporting a blood charge from a source to the cabinet;

a flask removably contained in said secure environment and coupled to the input system to receive said charge;

stressors coupled to the cabinet and positioned for operation to create a conditioned charge in the flask;

an output system coupled to the flask and including a receiver for the conditioned charge;

the apparatus being characterized by:

a control system contained in the cabinet and operable upon closing the door to lock the door and to then automatically condition the charge and to cause the charge to move from the flask to the receiver, whereby a charge from the input system is conditioned and delivered to the receiver, the door is then unlocked and the conditioned charge is ready to be removed and used to complete the medical procedure.

2. Apparatus as claimed in claim 1 in which the input system includes an input syringe operable to draw blood to form at least part of said charge, and input tubing connecting the input syringe to the flask to transport the charge into the flask.

3. Apparatus as claimed in claim 2 in which the input tubing is thermoplastic tubing, and in which the cabinet includes a first heat sealer operable to seal and sever the input tubing, whereby the input syringe can be separated from the cabinet and flask for subsequent disposal.

4. Apparatus as claimed in claim 2 in which the input syringe includes a valved T-connector having first and second ports so that the first port is available to draw the charge and the second port is attached to the input tubing for use to transport the charge to the flask.

5. Apparatus as claimed in claim 1 in which the flask has an internal volume significantly greater than the volume of the charge to permit the charge to bubble thereby increasing the surface area available for the stressors to condition the charge.

6. Apparatus as claimed in claim 1 in which the flask includes a main portion defining an internal volume to receive the charge and a connector assembly coupled to the main portion.

7. Apparatus as claimed in claim 6 and further including a probe coupled to the connector assembly and contained in the main portion, the probe extending to a leading end and having an input lumen coupled to the input system to deliver the charge into the internal volume and an output lumen coupled to the output system for delivering the conditioned charge to the output system.

8. Apparatus as claimed in claim 7 in which the probe further includes a gas lumen coupled to one of said stressors for delivering a gas stressor to the charge to cause the charge to bubble.

9. Apparatus as claimed in claim 7 in which the probe further includes a further lumen and a temperature sensor positioned in the further lumen for monitoring the temperature of the charge.

10. Apparatus as claimed in claim 7 in which the lumens extend to the leading

end.

11. Apparatus as claimed in claim 8 in which the lumens extend to the leading end.

12. Apparatus as claimed in claim 9 in which said further lumen ends adjacent said leading end at a side opening and in which the temperature sensor terminates in the side opening for better thermal contact with the charge.

13. Apparatus as claimed in claim 12 and further including a filmic sleeve surrounding the temperature sensor to avoid contact between the sensor and the charge

14. Apparatus as claimed in claim 9 in which the temperature probe further includes an extension engaged in said further lumen at the leading end of the probe and extending downwardly, and in which the flask includes a socket at the bottom of the main portion and extending downwardly to accommodate at least part of said extension to locate the probe in the main portion of the flask.

15. Apparatus as claimed in claim 14 in which the socket is crimped to hold the extension in the socket.

16. Apparatus as claimed in claim 1 in which one of said sensors is an infrared source positioned in the cabinet under the flask for radiating the charge to heat the charge in the flask.

17. Apparatus as claimed in claim 1 in which one of said sensors is an ultraviolet source positioned in the cabinet for subjecting the charge to ultraviolet light to stress the charge in the flask.

18. Apparatus as claimed in claim 1 and further comprising an oxygen source removably coupled to the cabinet, and an ozone generator coupled to the oxygen source to generate an ozone/oxygen mixture for delivery to the flask.

19. Apparatus as claimed in claim 1 in which the cabinet includes a cavity for receiving the flask in a downward movement, the cavity being positioned to locate the flask in relation to the stressors.

20. Apparatus as claimed in claim 1 in which the cabinet includes a front recess, and a top depression above the recess, the door being shaped to cover both the front recess and the depression when the door is in the closed position.

21. Apparatus as claimed in claim 1 in which the receiver is an output syringe.

22. Apparatus as claimed in claim 21 and further including an actuator attached to the cabinet and positioned to operate the output syringe as directed by the control system to first draw the conditioned charge from the flask and to then be used to inject the charge into the patient.

23. Apparatus as claimed in claim 21 and further including thermoplastic output tubing connecting the flask to the output syringe to transport the conditioned charge to the syringe.

24. Apparatus as claimed in claim 23 and further including a second heat sealer attached to the cabinet and positioned to be operated by the control system to seal and sever the output tubing between the flask and the output syringe.

25. Apparatus as claimed in claim 22 and further including a knocker attached to the cabinet and positioned to rap the output syringe to dissipate any bubbles in the conditioned charge contained by the output syringe.

26 Apparatus as claimed in claim 1 in which the control system includes an identification system for recognising a first identifier carried by the operator, and a second identifier carried by the patient, the identification system being adapted to recognise and to then permit the operator to operate the apparatus.

27. Apparatus as claimed in claim 1 and further including an operator card reader for reading discrete information on a card used to identify the operator of the apparatus to prevent unauthorized use.

28. Apparatus as claimed in claim 27 and further including a patient card reader for reading discrete information on a patient card used to identify the patient so that the patient can be identified by presentation of the patient card to the patient card reader.

29. Apparatus as claimed in claim 1 and further including a printer for providing a printout of data relating to the procedure for an individual patient.

30. Apparatus as claimed in claim 1 in which the control system includes a graphic display interface for the operator.

31. A cabinet for use in conditioning mammalian blood for subsequent use in a medical procedure, a blood charge being conditioned in a flask and the cabinet having:

a front defining a front recess;

a top defining a depression adjacent to the front recess;

a door hinged for movement between an open position and a closed position in which the front recess and the depression are covered by the door to create a secure environment;

a lock coupled to the cabinet and to the door to lock the door in the closed

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position;

a cavity extending downwardly from the top depression within the secure environment, the cavity being adapted to receive the flask;

said cabinet being characterized by:

a control system coupled to the door lock to sense the condition of the door to establish that the flask is securely positioned in the cabinet, and that the door is locked before the charge is conditioned.

32. A cabinet as claimed in claim 31 and further including a mount for a receiver which receives the conditioned charge from the flask, the mount being positioned in the front cavity.

33. A cabinet as claimed in claim 32 and further including a knocker mounted adjacent said mount in the front cavity and positioned for striking the receiver repetitively to break up bubbles in the conditioned charge.

34. A cabinet as claimed in claim 33 in which the knocker includes an impact tool mounted in the front cavity for striking the receiver from one side and a spring mounted in the cavity on the opposite side from the tool whereby when the tool impacts the receiver, the spring stores energy and rebounds to push the receiver towards the tool to start a new cycle.

35. A cabinet as claimed in claim 34 in which the knocker is coupled to the control system to cause the knocker to rap the receiver at a frequency of about one Hertz.

36. A cabinet as claimed in claim 31 and further including a mount in the front cavity for an output syringe which receives the conditioned charge from the flask, the syringe being held by the mount in the front cavity with the operator lowermost.

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37. A cabinet as claimed in claim 31 and further including an actuator in the front cavity for coupling to the operator to activate the output syringe to draw the conditioned charge into the syringe within the secure environment.

38. A cabinet as claimed in claim 31 and further including at least one heat sealer mounted for operation in the secure environment when the door is closed to sever thermoplastic tubing used to make connections to and from the flask.

39. A cabinet for use in conditioning mammalian blood for subsequent use in a medical procedure, a blood charge being conditioned in a flask and the cabinet having:

a front;

a top;

a door hinged for movement between an open position and a closed position in which at least a portion of the front and a portion of the top are covered by the door to create a secure environment;

a lock coupled to the cabinet and to the door to lock the door in the closed position;

a cavity extending downwardly from the top wall within the secure environment, the caity being adapted to receive the flask;

said cabinet being characterized by:

a control system coupled to the door lock to sense the condition of the door to establish that the flask is securely positioned in the cabinet, and that the door is locked before the charge is conditioned.

40. A cabinet as claimed in claim 39 and further including a mount for a receiver which receives the conditioned charge from the flask, the mount being positioned in the secure environment.

41. A cabinet as claimed in claim 40 and further including a knocker mounted adjacent said mount and positioned for striking the receiver repetitively to break

up bubbles in the conditioned charge.

42. A cabinet as claimed in claim 41 in which the knocker includes an impact tool for striking the receiver from one side and a spring mounted on the opposite side from the tool whereby when the tool impacts the receiver, the spring stores energy and rebounds to push the receiver towards the tool to start a new cycle.

43. A cabinet as claimed in claim 42 in which the knocker is coupled to the control system to cause the knocker to strike the receiver at a frequency of about one Hertz.

44. A cabinet as claimed in claim 39 and further including a mount on the front wall for an output syringe which receives the conditioned charge from the flask, the syringe being held by the mount with the operator lowermost.

45. A cabinet as claimed in claim 39 and further including an actuator on the front wall for coupling to the operator to activate the output syringe to draw the conditioned charge into the syringe within the secure environment.

46. A cabinet as claimed in claim 39 and further including at least one heat sealer mounted for operation in the secure environment when the door is closed to seal and sever thermoplastic tubing used to make connections to the flask.

47 A cabinet as claimed in claim 39 and further comprising an infrared source positioned below the cavity for operation to heat the charge when the flask is contained in the cavity to thereby condition the charge.

48. A cabinet as claimed in claim 39 and further comprising an ultraviolet source positioned about the cavity for operation to shine on the charge when the flask is contained in the cavity to thereby condition the charge.

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49. A cabinet as claimed in claim 39 and further comprising an ozone generator for receiving oxygen and converting at least some of the oxygen to ozone, and an ozone delivery system for coupling to the flask when the flask is in the cavity to bubble a mixture of ozone and oxygen into the charge to condition the charge.

50. A flask assembly for use in apparatus having a cabinet made to receive the flask assembly for conditioning mammalian blood, the flask assembly including:

a flask in the form of an envelope defining a substantially enclosed volume and including a top and a bottom, the top having an access opening and an outlet;

a connector assembly coupled to said top of the flask;

said flask assembly being characterized by a probe extending from the connector assembly, through the access opening and having a top end and a leading end, the probe being sealed in the access opening and defining an input lumen for transporting the charge to the bottom of the flask, an output lumen for transporting conditioned charge from the bottom of the flask out of the flask, and a gas lumen for feeding gas into the flask to condition the charge when a charge is in the flask;

the connector assembly including outlet tubing coupled to said outlet to lead spent gas out of the flask, and inlet tubing coupled to the gas lumen;

a pair of gas connectors coupled to the platform and connected to the respective gas inlet tubing and to the gas outlet tubing to make gas connections when the flask assembly is mounted in the apparatus, whereby as the flask is engaged in the cabinet the gas connectors engage a gas supply system for conditioning said charge in the flask before removing the conditioned charge.

51. A flask assembly as claimed in claim 50 in which said enclosed volume is in the order of about 70 times the volume of the charge to be entered into the flask.

52. A flask assembly as claimed in claim 50 in which the flask is of low density

polyethylene.

53. A flask assembly as claimed in claim 50 in which the platform includes an overhanging portion extending outwardly from said top, and in which the gas connectors are mounted on the overhanging portion and in which he gas supply system includes fittings mounted on the cabinet for engagement with the gas connectors when the flask is engaged in the cabinet.

54. A flask assembly as claimed in claim 51 and further including a cover attached to the platform to contain the platform and present a cleaner appearance.

55. A flask assembly as claimed in claim 54 in which the cover is attached to the flask.

56. A flask assembly as claimed in claim 55 in which the cover is a snap fit on the flask, and in which the cover and flask are arranged so that the cover fits on the flask with the outlet tubing aligned with the outlet in said top.

57. A flask assembly as claimed in claim 50 and further including in-line filters in the gas inlet tubing and in the gas outlet tubing, the in-line filters being mounted on the platform.

58. A flask assembly as claimed in claim 50 in which the flask defines an upper cylindrical portion and a smaller lower cup at the bottom of the flask, the cup being proportioned to receive the charge, and in which the leading end of the probe is contained close to said bottom.

59. A flask assembly as claimed in claim 50 in which the probe includes a further lumen containing a temperature probe for monitoring the temperature of the charge, the probe being located near the leading end of the probe.

60. A flask assembly as claimed in claim 59 in which said further lumen ends at a side opening in the probe, and in which the temperature probe is positioned in the opening for better thermal conductivity from the charge to the temperature sensor.

61. A flask assembly as claimed in claim 59 and further including a an extension engaged in the leading end of said further lumen and projecting downwardly, and in which the flask includes a socket at the leading end shaped to receive the extension to locate the leading end of the probe relative to the flask.

62. A flask assembly as claimed in claim 50 in which: the flask defines an upper cylindrical portion and a smaller lower cup at the bottom of the flask, the cup being proportioned to receive the charge, and in which the leading end of the probe is contained close to said bottom; and in which the flask assembly further includes an extension engaged in the leading end of said further lumen and projecting downwardly, and in which the flask includes a socket at the leading end shaped to receive the extension to locate the leading end of the probe relative to the cup.

63. A flask assembly as claimed in claim 62 in which the probe includes a further lumen containing a temperature probe for monitoring the temperature of the charge, the probe being located near the leading end of the probe.

64. A flask assembly as claimed in claim 63 in which said further lumen ends at a side opening in the probe, and in which the temperature probe is positioned in the opening for better thermal conductivity from the charge to the temperature sensor.

65. A flask assembly as claimed in claim 50 in which the probe includes a

further lumen containing a temperature probe for monitoring the temperature of the charge, the probe being located near the leading end of the probe, and in which the platform includes an overhanging portion extending outwardly from said top, and electrical contacts mounted on the overhanging portion for engagement automatically with suitable fittings mounted on the cabinet when the flask is engaged in the cabinet.

66. A flask assembly as claimed in claim 65 in which: the flask defines an upper cylindrical portion and a smaller lower cup at the bottom of the flask, the cup being proportioned to receive the charge, and in which the leading end of the probe is contained close to said bottom; and in which the flask assembly further includes an extension engaged in the leading end of said further lumen and projecting downwardly, and in which the flask includes a socket at the leading end shaped to receive the extension to locate the leading end of the probe relative to the cup.

67. A flask assembly as claimed in claim 65 in which said further lumen ends at a side opening in the probe, and in which the temperature probe is positioned in the opening for better thermal conductivity from the charge to the temperature sensor.

68. A flask assembly as claimed in claim 50 and further comprising input and output syringes releasably mounted on the connector assembly, the input syringe being connected to the input tubing and the outlet syringe being connected to the output tubing.

69. A process of treating mammalian blood in a blood charge to provide a conditioned charge for giving to a patient in a medical procedure, the process including the steps:

providing an automatic apparatus for treating the blood charge to create

said conditioned charge, and for presenting the conditioned charge ready for use, the apparatus having a secure environment, a door controlling access to the environment, a flask and stressors arranged to operate on a charge in the flask in the controlled environment;

transporting the blood charge into the secure environment through thermoplastic inlet tubing for deposit in the flask;

sealing and severing the inlet tubing;

removing part of the inlet tubing outside the secure environment;

initiating the operation of the automatic apparatus so that the stressors will operate on the charge for a predetermined period, thereby stressing the charge in the flask while maintaining the secure environment;

allowing the apparatus time to transport the conditioned charge from the flask to a receiver; and

opening the door to provide access to the receiver for use to give the conditioned charge to the patient.

70. A process as claimed in claim 69 and further including the step of providing an identification system operable to control the door so that the door will prevent entrance to the controlled environment unless actuated by the identification system.

71. A process as claimed in claim 69 and further including the steps of transporting the conditioned charge through thermoplastic outlet tubing, and sealing and severing the outlet tubing after the conditioned charge is in the receiver to separate the receiver for use to give the conditioned charge to the patient.

72. A process as claimed in claim 69 and further including the step of providing an identifier for the patient, the identifier being operable to control the door so that the door will prevent entrance to the controlled environment unless

actuated by the patient identifier.

73. A process as claimed in claim 70 and further including the steps of transporting the conditioned charge through thermoplastic outlet tubing, and sealing and severing the outlet tubing after the conditioned charge is in the receiver to separate the receiver for use to give the conditioned charge to the patient.

74. A process as claimed in claim 69 and further including the steps of providing an identifier for the patient, and a separate identifier for an operator, the identifiers being operable in combination to control the door so that the door will prevent entrance to the controlled environment unless actuated by a combination of the patient identifier and the operator identifier.

75. A process as claimed in claim 74 and further including the steps of transporting the conditioned charge through thermoplastic outlet tubing, and sealing and severing the outlet tubing after the conditioned charge is in the receiver to separate the receiver for use to give the conditioned charge to the patient.

76. A process as claimed in claim 70 in which the identification system includes smart cards operable to control the door so that the door will prevent entrance to the controlled environment unless actuated by the identification system, and in which the smart card receives a record of the process after completion of the process.

77. A process as claimed in claim 70 in which the identification system includes a patient smart card and an operator smart card, the smart cards being operable in combination to control the door so that the door will prevent entrance to the controlled environment unless actuated by the use of the smart cards in

combination.

78. A process as claimed in claim 77 in which at least one of the smart cards receives a record of the process after completion of the process.

79. A cabinet as claimed in claim 34 further comprising a bubble sensor for detecting bubbles in the conditioned charge, the knocker operable to strike the receiver and break up bubbles on the bubble sensor sensing said bubbles.

80. A cabinet as claimed in claim 43 further comprising a bubble sensor for detecting bubbles in the conditioned charge, the bubble sensor being electrically coupled to the control system, whereby the control system activating the knocker to strike the receiver on the bubble sensor detecting said bubbles.

81. A cabinet as claimed in claim 46 further including a seal locator associated with said tubing, said seal locator being cooperable with said at least one heat sealer to assist on the positioning of said tubing therein.

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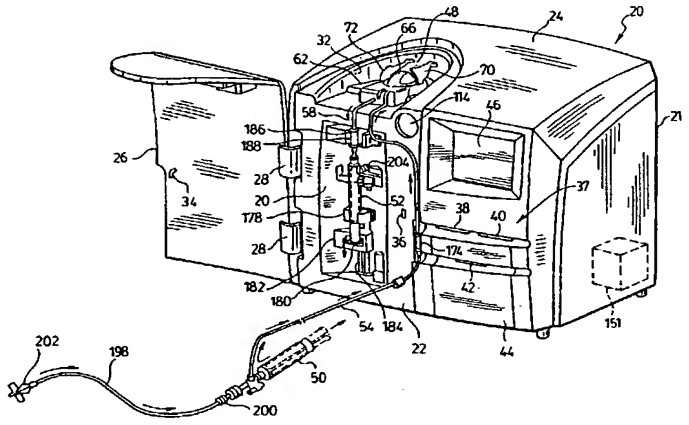
(54) Title: APPARATUS AND PROCESS FOR CONDITIONING MAMMALIAN BLOOD



(57) Abstract: The invention provides apparatus (20) for conditioning mammalian blood for subsequent use in a medical procedure. The apparatus includes a cabinet (21) having a secure environment and a door (26) providing the only access to the environment. An input system is provided for transporting a blood charge from a source to the cabinet (21) and a flask (56) is removably contained in the secure environment and coupled to the charge input system to receive the charge. Stressors (86, 88) are coupled to the cabinet (21) and positioned for operation to create a conditioned charge in the flask (56). An output system is coupled to the flask and includes a receiver (52) for the conditioned charge. The apparatus (20) includes an automated control system (151) operable upon closing the door (26) to lock the door and to then condition the charge, and to then cause the charge to move from the flask to the receiver. As a result, a charge from the input system is conditioned and delivered to the receiver, the door is then unlocked and the conditioned charge is ready to be removed and used to complete the medical procedure. A flask assembly (48) is also provided for use in the apparatus (20) and a process is also described.

WO 01/19318 A1

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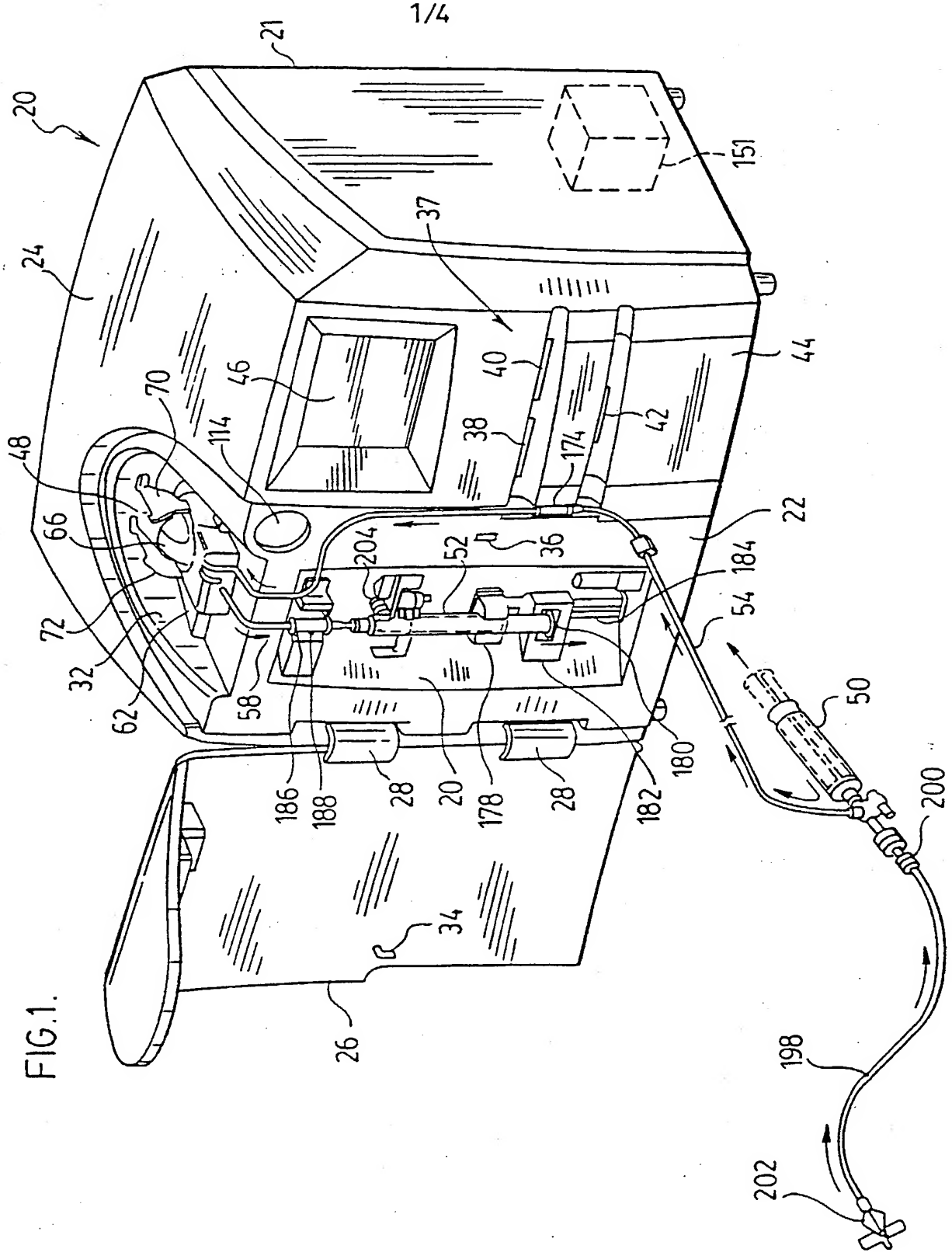
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FIG.1.

FIG. 2.

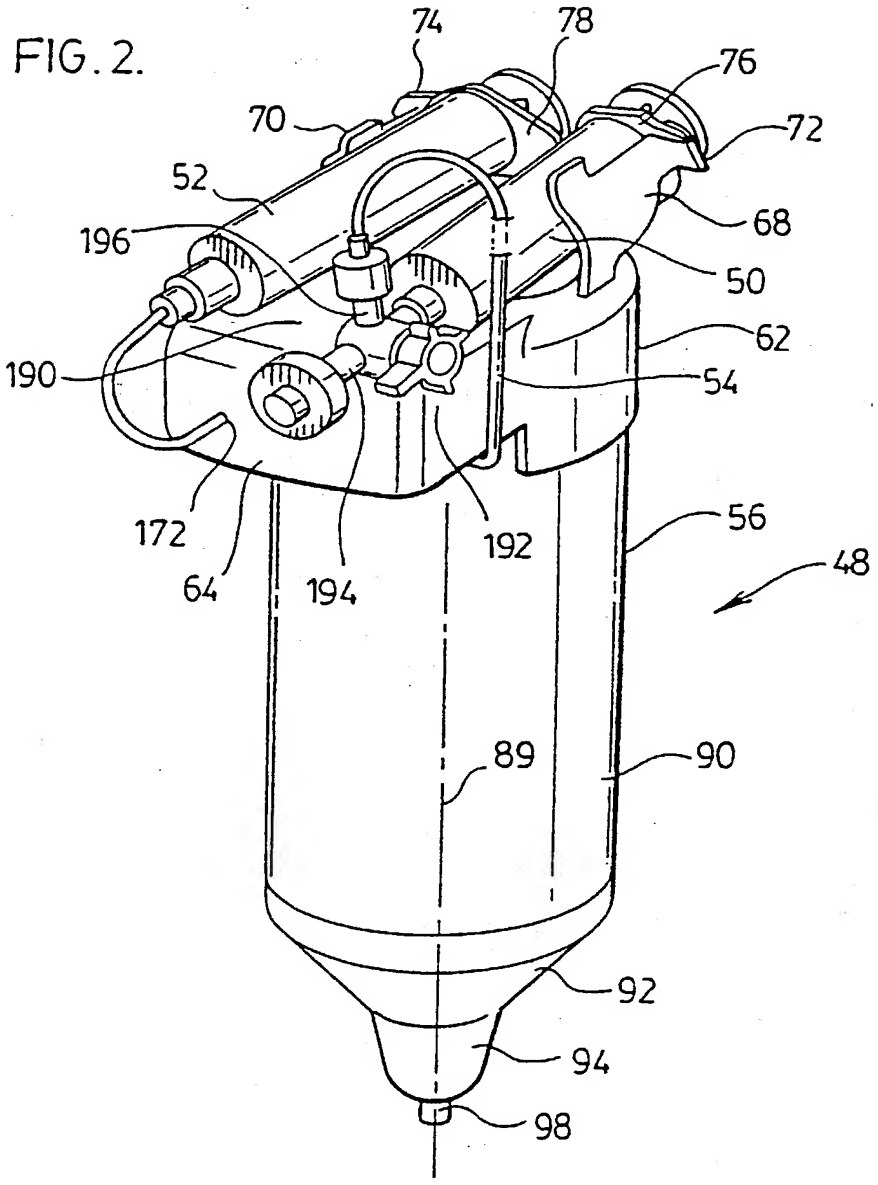
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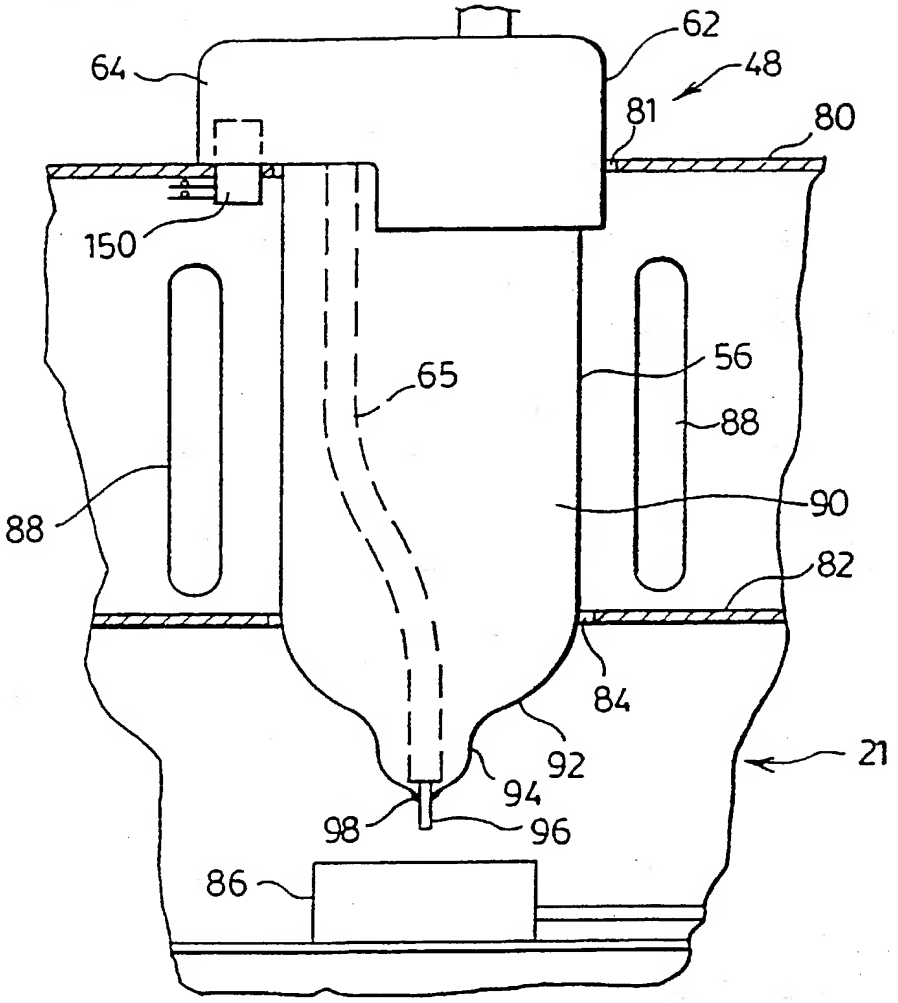
FIG. 3.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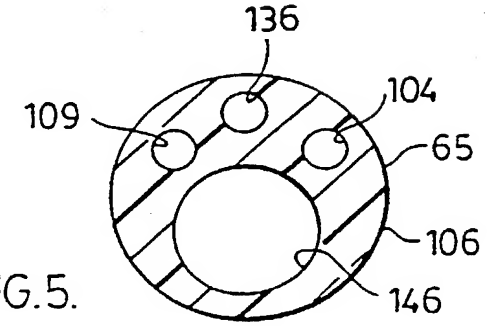
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FIG. 5.

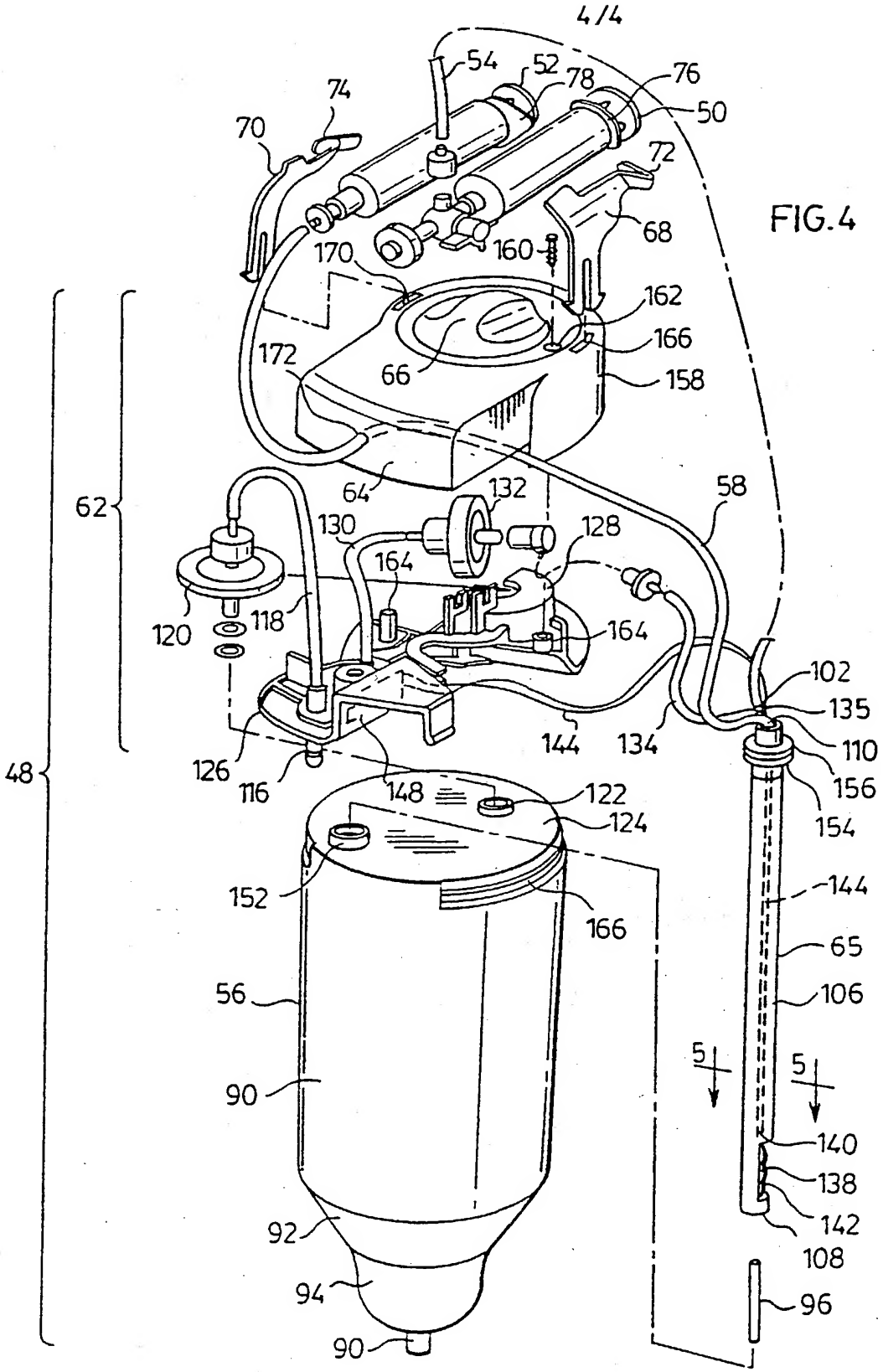
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FIG.4

10088351 .092602 #4

033136-260
Attorney's Docket No.

COMBINED DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

APPARATUS AND PROCESS FOR CONDITIONING MAMMALIAN BLOOD

the specification of which (check only one item below):

☐ is attached hereto.

☒ was filed as United States application
Number 10/088,351 on March 15, 2002
and was amended on _____ (if applicable).

☒ was filed as PCT international application
Number PCT/CA00/01078 on September 15, 2000
and was amended on November 28, 2001 (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §§119 (a)-(d), 172 or 365 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. §§119(a)-(d), 172 or 365:				
COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C. §§119, 172 or 365	
PCT	PCT/CA00/01078	15 September 2000	X Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No

I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

William L. Mathis	17,337	Eric H. Weisblatt	30,505	Bruce T. Wieder	33,815
Robert S. Swecker	19,885	James W. Peterson	26,057	Todd R. Walters	34,040
Platon N. Mandros	22,124	Teresa Stanek Rea	30,427	Ronni S. Jillions	31,979
Benton S. Duffett, Jr.	22,030	Robert E. Krebs	25,885	Harold R. Brown III	36,341
Norman H. Stepno	22,716	William C. Rowland	30,888	Allen R. Baum	36,086
Ronald L. Grudziecki	24,970	T. Gene Dillahunty	25,423	Brian P. O'Shaughnessy	32,747
Frederick G. Michaud, Jr.	26,003	Patrick C. Keane	32,858	Kenneth B. Leffler	36,075
Alan E. Kopecki	25,813	B. Jefferson Boggs, Jr.	32,344	Fred W. Hathaway	32,236
Regis E. Slutter	26,999	William H. Benz	25,952	Wendi L. Weinstein	34,456
Samuel C. Miller, III	27,360	Peter K. Skiff	31,917	Mary Ann Dillahunty	34,576
Robert G. Mukai	28,531	Richard J. McGrath	29,195	Donna M. Meuth	36,607
George A. Hovanec, Jr.	28,223	Matthew L. Schneider	32,814	Mark R. Kresloff	42,766
James A. LaBarre	28,632	Michael G. Savage	32,596		
E. Joseph Gess	28,510	Gerald F. Swiss	30,113		
R. Danny Huntington	27,903	Charles F. Wieland III	33,096		

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00

FULL NAME OF SOLE OR FIRST INVENTOR	Sonya MONTGOMERY
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I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

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Norman H. Stepno	22,716	William C. Rowland	30,888	Allen R. Baum	36,086
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☒ Additional inventors are being named on the Supplemental Additional Inventor(s) Sheet(s) attached hereto.

FULL NAME EIGHTH INVENTOR, IF ANY	Jeff DAYMAN
Signature	
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☒ Additional inventors are being named on the Supplemental Additional Inventor(s) Sheet(s) attached hereto.

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Residence (City, State, Country)	Waterloo, Ontario, CANADA
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Mailing Address	90 Rose Lea Crescent
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FULL NAME NINTH INVENTOR, IF ANY	Thomas PORTER
Signature	Thomas Porter Aug 16/02
Date	
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Date	Sept 5/02
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☒ Additional inventors are being named on the Supplemental Additional Inventor(s) Sheet(s) attached hereto.

COMBINED DECLARATION FOR PATENT APPLICATION & POWER OF ATTORNEY (Includes Reference to Provisional and PCT International Applications) **Supplemental Sheet**	Attorney's Docket No. 033136-260

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Citizenship	
Mailing Address	
City, State, ZIP, Country	
Full Name of Additional Joint Inventor, If Any	
Signature	
Date	
Residence (City, State, Country)	
Citizenship	
Mailing Address	
City, State, ZIP, Country	

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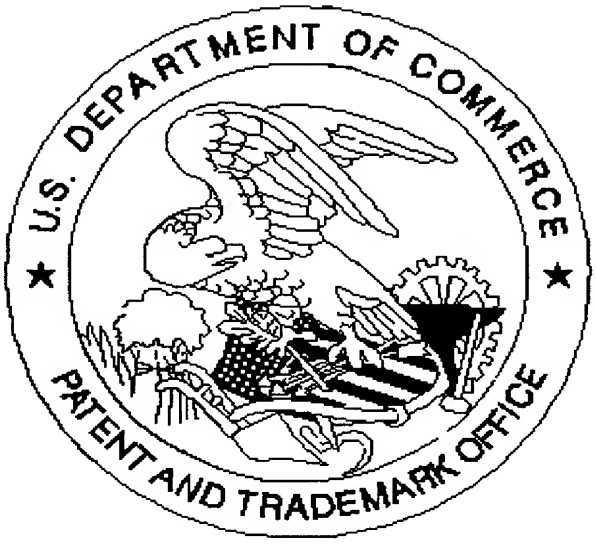
United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division



Application deficiencies found during scanning:

☑ Page(s) 5 of 5 of declaration was ~~were~~ not present for scanning.
(Document title)

☐ Page(s)_____ of_____ were not present for scanning.
(Document title)

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